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Biota Holdings Limited
10/585 Blackburn Road
Notting Hill, VIC 3168

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Biota Holdings Limited (ASX: BTA) yesterday reported a net loss after tax of \$6.5 million, compared with net profit of \$20.2 million in the previous year. The result included litigation costs of \$21.8 million, up from \$10.4 million. Can you provide any guidance on the outlook for earnings in the current year ending June 2009?

CEO Peter Cook

Our earnings are heavily influenced by our receipt of Relenza royalties. GlaxoSmithKline (GSK), our licensee, has described the government stock pile market for Relenza as a swing factor in its own performance in its current December 2008 financial year. GSK referred to announcements from a number of governments that they would increase their national stock piles of neuraminidase inhibitors but pointed out that it remained unclear when orders would be placed. Given GSK can't provide its own shareholders with any better guidance, it would be inappropriate for me to give a different view.

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You've also announced that your collaboration and licence agreement with MedImmune Inc. for antivirals for the treatment of respiratory syncytial virus (RSV) has been assigned to AstraZeneca, which acquired MedImmune in 2007. AstraZeneca has also secured rights to the RSV program in a number of territories previously held by Biota, for which Biota will receive an additional US\$3.5 million plus royalties. What's the strategic rationale of ceding the additional territories to AstraZeneca?

CEO Peter Cook

AstraZeneca is a global pharmaceutical company, as distinct from MedImmune which was a North American specialty pharma at the time we licensed the RSV program. We recognised the value of those Asia/Pacific territories to a global company, but it was perhaps not so evident to a regionally focused specialty pharma group. The territories add value to AstraZeneca, particularly given its commitment to antiviral development. Our business is to license drug development projects to pharmaceutical companies, and the territories presented an opportunity for us to increase our returns.

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What was AstraZeneca's process for evaluating the RSV program and why did it wish to extend the scope of the original agreement?

CEO Peter Cook

AstraZeneca evaluated the RSV program as part of its due diligence prior to its acquisition of MedImmune. Not surprisingly, we weren't privy to any aspect of that process. However, we know AstraZeneca was particularly interested in RSV. At about the time it acquired MedImmune, it acquired a smaller UK-based drug discovery company, Arrow Therapeutics, whose lead candidate was an RSV compound licensed to Novartis. Arrow has other small molecule RSV antiviral programs which no doubt also held some interest for AstraZeneca, hence the acquisition.

The scope of the original agreement has been extended not only through an expansion of the territories as I've outlined, but also through more extensive research input from us. The increased research activity is intended to accelerate the program, which was seen as very desirable by AstraZeneca.

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You've indicated that under the agreement, all existing milestone and royalty entitlements are preserved as well as Biota's R&D program being extended. The original agreement was estimated to be worth US\$107 million in milestones. What is the value of the extended agreement and what will it mean for revenues in the short to medium term?

CEO Peter Cook

The original agreement was for \$US5 million up-front and up to \$107.5 million on the delivery of certain clinical, regulatory and sales milestones. The extended agreement sees the up-front payment increased by \$US3.5 million, and although the milestone targets haven't changed under the new agreement, they become easier to achieve, particularly the sales milestones.

The rate at which royalties are payable, if the product does achieve sales, also won't alter, although they'll be payable now on a much larger territory base, which will include India, China, Australia, New Zealand, the ASEAN countries and a string of smaller Asian countries. The extended agreement will also increase our collaboration income in the near term. This income wasn't included in the original \$US107.5 million.

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In July you announced the conclusion of your litigation against GSK through mediation. The agreement provided for a \$20 million payment to Biota, with each party bearing its own legal costs. Given you claimed losses of \$564 million to \$704 million in relation to GSK's failure to use its best endeavours in the development of Relenza, why did you settle for a much lower amount?

CEO Peter Cook

On 27 May, the Supreme Court set aside the previously scheduled trial date of 4 August. After that, the view of our legal advisors was that a trial was potentially 12 to 18 months away and perhaps even as late as 2010. Such a delay would necessitate further costs, potentially well in excess of the total incurred to date. Furthermore, the trial itself could be expected to run for six to nine months, with additional costs associated with that, not to mention the possibility of additional costs and time associated with any appeal. To see the process through, we were looking at a funding level of up to \$100 million. In those circumstances, we saw that settlement best met our objective of balancing the risk and cost the litigation posed with the expected rewards.

The claimed losses you mentioned have caused considerable confusion. They were a damages claim, and were for interlocutory purposes before the court and most closely resemble a whole-of-life valuation. They were never a 'settlement amount', which many thought them to be. They were an estimate of the total royalty stream from Relenza, in an ideal, competitive market, from the date of launch to the date of termination of the last patent.

There are a number of reasons the settlement amount would never even closely approach those numbers, including that the Relenza patent still has six years before expiry, on which no royalties have yet been paid. To compare the damages claim figure with the settlement outcome you'd value the latter by adding \$20 million for the settlement to the \$60 million of royalties received to date, plus an estimate of the next six years' royalties of \$120 million to \$240 million (based on the last two years), a total of potentially \$320 million or more.

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When will the settlement be received and what is the basis of your estimate that the case will result in a net inflow of approximately \$12 million in the current year?

CEO Peter Cook

The settlement has already been received, and the impact has been fully outlined as an event subsequent to balance date in our annual accounts which were released on Monday 25 August. As soon as it was apparent the mediation had brought a resolution, all costs were stopped as quickly as possible, but costs will be incurred in fiscal 2009. The net inflow you've identified includes our estimate of the payments yet to be invoiced by those who'd been working on the case on our behalf, including expert witnesses, barristers, lawyers, discovery teams and other non-legal advisors.

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What implications does the settlement have for future sales and royalty streams from Relenza?

CEO Peter Cook

Our royalties are linked to sales of Relenza by GSK and the settlement agreement has no direct impact on either sales or royalty rates.

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Revenue, excluding interest income, was \$41.8 million in 2008, down 24 percent from the previous year reflecting a 32 percent drop in Relenza royalties to \$20.5 million. What was the reason for the decline in Relenza sales? Did the sales trend have any bearing on your willingness to settle the litigation with GSK?

CEO Peter Cook

Sales of Relenza proved volatile over the course of the year with poor third and fourth quarters. JP Garnier, GSK's recently retired CEO, identified in January the difficulties the government stock-piling market was presenting, including in forecasting for supply and in reliability and consistency of orders.

There's little doubt the threat of an influenza pandemic remains real and neuraminidase inhibitors are the best front-line product to stock pile for a quick response. Few governments have yet stock piled sufficient product to protect a significant portion of their populations for an adequate period of time, yet orders appear to be uncertain. These features of government procurement aren't assisting the development of a stable market with reliable supply characteristics for either GSK or its major competitor Roche.

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Biota had cash flow from operations of \$4.8 million in 2008, down from \$21.0 million in the previous year. Cash stood at \$60.2 million at 30 June 2008, down from \$62.2 million a year earlier. What is the outlook for cash flow following the completion of the GSK litigation?

CEO Peter Cook

The resolution of the litigation has removed a significant expense but cash is principally driven by Relenza royalties, which will remain difficult to forecast. It will be the third quarter of fiscal 2009 before we get some clarity on likely Relenza royalties for the year. Nevertheless our cash balance gives us confidence to continue to invest in advancing our project portfolio in the near term. And while we remain confident regarding the medium term, we'll have to manage cash volatility as part of our overall project management considerations.

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You've announced the recommencement of your share buy-back, which was halted in May. Under the buy-back you plan to buy up to 5 percent of shares on issue. How does using cash in this way fit with your ongoing drug development priorities?

CEO Peter Cook

Our primary objective is to maximise the value of our project portfolio, and drug discovery and development is the core of our activity. We've reported considerable positive news over the last year or so, including an RSV program milestone payment for the commencement of Phase I clinical trials, the commencement and completion of long acting neuraminidase inhibitor (LANI) Phase II trials in Japan, as well as indicating the commencement of Phase III in the near future. We've also announced the commencement of human rhinovirus (HRV) Phase IIa studies in the UK, the resolution of the litigation with GSK, and of course the assignment of the RSV program to AstraZeneca plus the territory and program expansion.

Despite this significant progress, there has been no response in our stock price. Under these circumstances, we believe that resuming the share buy-back will create some value for all our shareholders without excessively limiting our ability to grow and develop our project portfolio.

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What potential milestones do you expect over the next 12 months?

CEO Peter Cook

We expect our major milestones over the next year or so to include: renewal of the board given the retirements recently announced; tight management of our cash; completion of the HRV Phase IIa study; reinstatement of the on-going management contact and commercial arrangements with GSK, including advice on quarterly Relenza royalties; commencement of the LANI Phase III studies; and completion of the RSV Phase I study. We'd also expect to continue to deliver our ongoing programs to the satisfaction of our licensees, and when appropriate, to secure licensees for additional programs.

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Thank you Peter.

For more information about Biota, visit www.biota.com.au or call CEO Peter Cook on +61 3 9915 3720 or CFO Damian Lismore on +61 3 9915 3721.

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